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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,142	06/26/2006	Tadayuki Tokunaga	292949US0PCT	5697

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,142	TOKUNAGA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/04/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of IDS and **RCE** filed on 10/04/10 is acknowledged.

Claim 1 has been amended.

Claim 4 has been withdrawn.

New claims 18-25 have been added.

Accordingly, claims **1-3 and 5-25** are under prosecution.

The rejections not reiterated herein have been withdrawn in light of claims amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 5-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of chelating agent less than 0.1% which makes the claim indefinite because less than also means without chelating agent or it also means that mount that is 0.0001%, thus the metes and bounds of claim is not defined. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5-10, 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forward et al. (US 4,193,988) in view of Lee et al. (USP 6,214,321).

Forward et al. disclose oral hygiene compositions comprising a mixture of calcium glycerophosphate (calcium ion supplying compound) and sodium monofluorophosphate (a monofluorophosphate compound). The compositions may be formulated into powders, pastes, gels or liquids (Abstract). The activity of sodium monofluorophosphate in reducing the solubility of tooth enamel is enhanced or potentiated when used in admixture with certain proportions of calcium glycerophosphate (col. 1, lines 22-26). The sodium monofluorophosphate and calcium glycerophosphate in the ratio of 10:1 to 3:1 are present in composition. The calcium glycerophosphate is at 0.2% and sodium monofluorophosphate is at 0.8%, see column 1, lines 64-65. The composition is in the form of paste, gel liquid or powder, abstract. The compositions may also comprise other calcium salts. The reference does not comprise phosphate ion supplying compound and disclosed above the calcium ion supplying compound and monofluorophosphate ion supplying compounds are different.

The liquids in the dental cream comprise chiefly water, glycerol and sorbitol (humectant). The amount is usually in range of 10%, preferable from 0.5% to 5.0% by weight of tooth paste, see column 2. A suitable surfactant can be added such as sodium lauryl sulfate, see column 2, lines 28-30 and examples. The pH of dental cream is of about 6 to 8, if desired a small amount of acid such as citric acid cam ne added, see column 2, lines 63-65. Various forms of composition can be mouth washes, chewing gum, lozenges, tablets, pastilles etc. see column 3, lines 7-13. The reference does not teach chelating agents (reads on the claimed 0.01% or less of chelating agent as claimed in instant claims 10 and 13).

While the reference teaches utilizing citric acid for pH adjustment, the reference does not teach utilizing the claimed lactic acid, malic or tartaric acid in the composition.

'321 teaches remineralization of teeth comprising calcium salt such as calcium phosphate and (calcium glycerophosphate) salts from amounts ranging from 0.01% to 30%, preferably from 0.1% to 20%, see title, column, 3 lines 10-15 and 30-32. The reference teaches that acidity of the composition can be adjusted with acids such as citric acid, lactic acid, malic acid or tartaric acid in an amount ranging from 0.1% to 20%, preferably from 0.5% to about 10%, see column 4, lines 10-20.The second composition comprises monofluorophosphate such as sodium and stannous and sodium fluoride which provides fluoride ions from about 25 to 5000 ppm of fluoride ions, see column 3, lines 53-55. The composition can be in the form of tooth paste, gel, powder or mouth wash, see column 3, lines 62-64. The first composition has lactic or

malic acid or acid salts may also be applied. See column 4, lines 12-14. Humectants such as sorbitol, mannitol and maltitol are disclosed in column 4, lines 26-33.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have utilized lactic acid or malic acid or tartaric acid in the composition of Forward et al. because Lee teaches equivalency among various acids which are used as pH regulating agents. Utilization of known pH adjusting agent such as lactic acid or malic acid would have been obvious to o ne of ordinary skill in the composition of Forward et al. with an expectation of obtaining predictable results, in the instant case utilization of lactic acid for pH adjustment would have been obvious to one of ordinary skill in the art. Regarding the claimed property of the composition that the composition does not settle and does not precipitate crystals after storage at 40 degrees Celsius for two weeks and has a residual factor of calcium ions of 76% or more after storage at 50 degrees Celsius for one month, it is reasonable to conclude that the compositions of the combined teachings will have these properties because the compositions of the reference may comprise substantially the same components, a calcium ion supplying compound, a monofluorophosphate ion supplying compound of the instant claims and therefore upon mixing the two components calcium glycerophosphate and monofluorophosphate similar product will be formed comprising substantially similar properties as claimed. Since the claimed components of the oral composition are obvious in light of the teachings of prior art, one would expect the properties to be similar as claimed absent evidence to contrary.

It is to be noted that while the prior art by Forward and Lee teach inclusion of calcium glycerophosphate in the composition, however, the references do not state the instantly claimed calcium ions to be from 100 to 16000 ppm. To that end, the reference of Lee teaches the amount of calcium supplying compounds to be from 0.1% to 20% as discussed above, since the instant specification uses 1% of calcium ion supplying compound in Table 1 on page 12, it is the position of the Examiner that prior art's range of calcium ion supplying compound that is from 0.1% to 20% will supply the claimed amount of calcium ions that is from 100 to 16000 ppm absent evidence to contrary. (It is to be noted that it is known in the dental art for remineralization that monofluorophosphate supplies monofluorophosphate ion first and then fluoride ion, it is the fluoride ion that is measured to check the concentration in ppm for monofluorophosphate compounds, USP PG pub. 20060099153, see paragraph [0021] and US PG pub. 20030170185, see examples 31-32 under ingredients under sodium monofluorophosphate, the concentration in terms of fluoride ion is 950 ppm.). Thus since the prior art teaches the calcium ion supplying compound, optimization of amount of such compound for the optimum release of calcium ions would have been obvious to one of ordinary skill by performing experimental manipulations. Regarding amount of various calcium or sodium monofluorophosphate, reference teaches various amounts as discussed above, experimentation with workable amounts in order to obtain best possible results would have been obvious over the teachings of prior art absent indication of unexpected results.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Forward et al. (US 4,193,988) in view of Lee et al. (USP 6,214,321) as discussed above and further in view of (Takatsuka et al. (USP 7,300,645).

The references discussed above do not teach using silicic anhydride in composition. Takatsuka et al. while teaching oral composition for remineralizing properties teach inclusion of silicic anhydride in the tooth paste formulation, see examples 21-22.

It would have been obvious too ne of ordinary skill in the art at the time of instant invention to have incorporated art recognized ingredients in tooth paste formulation contemplated in light of teachings of Forward and Lee et al. One of ordinary would have been motivated to do so because Takatsuka teaches a tooth paste formulation comprising silicic anhydride which is intended to be used for remineralization of tooth. Utilization of known ingredient would have resulted in predictable results that are a tooth paste composition with better remineralization properties absent evidence to contrary.

Response to Arguments

7. Applicant's arguments filed 10/04/10 have been fully considered but they are not persuasive.

Applicant argues that the present application describes an invention in which a chelating agent (e.g., citrate) is preferably not substantially added. In this aspect of the invention, *avoiding* the chelating agent prevents the decrease of calcium ion concentration. This in turn allows improved remineralization of teeth (see paragraphs [0012] and [0016] of the PG publication (i.e., US 2007/0128131)).

These arguments are not persuasive because the instant claims do recite presence of chelating agent in an amount of 0.1% by weight, while the arguments are true for no presence of chelating agent such as citrate, the results discussed do not commensurate with entire scope of all the chelating agents and with the amount claimed that is 0.1%.

Applicant argues that the Forward patent describes a different composition; namely, a composition in which pH is controlled by *adding* substances such as citric acid (see column 2, lines 62-65 of the Forward patent). Forward does not appreciate and does not disclose the difficulties encountered when sodium monofluorophosphate is used in combination with calcium glycerophosphate and thus does not appreciate the chelate-avoidance aspect of the present invention. Applicants on the other hand disclosed the difficulties associated with using sodium monofluorophosphate in admixture with a calcium ion-supplying compound (see for example paragraphs [0003] and [0011] of the PG publication). Citric acid in particular binds strongly to calcium ions to thereby chelate the calcium ion and make the calcium unavailable for the purpose of

remineralizing teeth. The invention described in the present claims avoids this undesirable function of chelation by requiring that chelating agents such as citrate (e.g., a salt or ester derived from citric acid) are included in an amount of no more than 0.1 wt%. This requirement of the present claims is directly contradictory to the Forward disclosure in which citric acid (e.g., a progenitor of the citrate chelating agent) is added to control pH (see column 4, second paragraph of Forward). Applicants disclosed a composition which permits the stable supply of calcium ions for the remineralization of teeth by using a particular acid to control the pH to 4-6.2. Forward describes modifying the acidity of compositions with an acid agent (e.g., citrate). In contrast, the present claims restrict the amount of chelating agent (e.g., citrate) to no more than 0.1%.

These arguments are not persuasive because the instant claims recite presence of chelating agent in 0.1% and thus read on prior art's agent. Besides as discussed above the remineralization improvement results discussed by applicants do not commensurate with scope of instant claims because claims recite presence of chelating agent in addition to being devoid of chelating agent. The prior art teaches and makes obvious the claimed invention, motivation to combine the prior art's teachings need not be same as applicants motivation for the invention. A comparative analysis with scientific and technical results to prove unexpected results has not been provided which results also commensurate with the entire scope of claims, as such the rejection is maintained. The results discussed are with only specific chelating agent citrate whereas instant claims encompass various chelating agents and reads on any amount less than 0.1%. Regarding Lee , Lee has been combined for modifying acidity of the composition

with lactic, malic or tartaric acid. As discussed earlier applicant's motivation to use specific pH need be same as motivation to combine in an obvious manner, in the instant case Lee teaches lactic acid etc. for modifying pH and modification of pH or adjustment of pH to obtain best possible results would be with in skill of an artisan.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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